

REMARKS

In the final office action, the Examiner holds that claims 1-24 and 26-30 are obvious, with reference to Schneider (US Patent No. 5,393,530), over Slater (US Patent No. 6,355,268) by itself or further in view of Zalipsky (US Patent No. 6,051,251) or Leigh (US Patent No. 5,004,611) and Suddith (US Patent No. 5,556,580), despite the irrelevance of the main objectives of the cited documents.

The examiner rejected claim 1 as being unclear as to how much the extrusion speed is increased to and the extrusion pressure lowered to. The applicant further limited claim 1 with the values of the extrusion pressure and the extrusion speed disclosed in paragraphs 0056 and 0076 of the specification as published in US 2005/0129750 A1. The specification disclosed that the present invention contributes to the prior art by lowering the extrusion pressure lower than 10 kg/cm² (142 psi) and increase the extrusion speed higher than 2 L/minute. The applicant asserts the amendment has sufficiently clarified claim 1 so to particularly point out and distinctly claim the subject matter, which the applicant regards as the invention.

The applicant further limited claim 1 with the limitation of the original claim 9 defining a range of the ratio of the alcohol solvent to the compounds (i), (ii) and (iii). The amendment to claim 1 is within the disclosure of the original specification. No new matter has been added.

The examiner deemed obvious manipulating the ratio of the alcohol solvent to the compound (i), (ii) and (iii) and stating that one of ordinary skill in the art can obviously modify the invention of Slater to include features of the inventions of Zalipsky or Leigh and Suddith.

Slater is considered to disclose a process of preparation of liposomes and Zalipsky is considered to show removal of small molecular weight compounds by means of dialysis or diafiltration. Both failed to teach a suitable ratio of the alcohol solvent to the compound (i), (ii) and (iii) for increasing extrusion speed higher than 2 L/minute and lowering extrusion pressure less than 142 psi.

Schneider simply states that "[E]xtrusion of empty liposomes is easy because of their inherent low viscosity", however is considered to teach to the connection between the viscosity and extrusion process for the putative provision of a connection of viscosity and the extrusion process. Schneider fails to teach manipulation of alcohol solvent ratio as a means to modify a solution with suitable viscosity for increasing extrusion speed higher than 2 L/minute and lowering extrusion pressure less than 142 psi.

Suddith is considered to teach fluid viscosity affects the extrusion rate that one skilled artisan will be able to increase the amounts of alcohol to reduce viscosity in a extrusion process. Nevertheless, Suddith failed to teach suitable alcohol solvent ratio for increasing extrusion speed higher than 2 L/minute and

lowering extrusion pressure less than 142 psi, which, according to the rejection reason under 35 USC §112 in the office action for the present invention, is indispensable to grasp the technical features. Thus the applicant believe that the present invention is not obvious to a skilled artisan over Slater itself or in view of Zalipsky, even with reference to Schneider or Suddith.

Leigh is considered to teach a range of the ratio of the lipid component to water-miscible component, which may be ethanol. Leigh, though disclosed a range of the ratio of the ethanol to lipid solution, failed to specifically teach suitable alcohol solvent ratio to compounds (i), (ii) and (iii) for increasing extrusion speed higher than 2 L/minute and lowering extrusion pressure less than 142 psi.

As an example of commercially feasible embodiment, the applicant current practice the method of the present invention to produce liposomes with extrusion pressure lower than 88 psi and at extrusion speed of 5 L/minute. Said example is covered in the scope of the present invention but not disclosed or taught by Leigh. The applicant asserts that one skilled artisan is not able to acquire a process with extrusion pressure lower than 142 psi and at extrusion speed higher than 2 L/minute even based on the disclosure of Leigh.

For the foregoing reasons, the applicant asserts that claim 1 is sufficiently clarified and not obvious over the cited documents and thus patentable. Claims 2-24 and 26-30, which are directly or indirectly dependent on the patentable

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claim 1, comprise the patentable subject matter and are also believed to be patentable.

After the foregoing arguments, the applicant asserts that the referenced application is patentable in view of the requirement of the office action and an early granting of the application is respectfully requested.

No fees are believed to be due with this Amendment. If there are any charges associated with this filing, the Honorable Director of Patents and Trademarks is hereby authorized to charge Deposit Account #50-5298 for such charges.

This Amendment was prepared by Applicant, and is being submitted without substantive change by the undersigned Attorney.

Respectfully submitted,
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Date